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FORMULATION, DEVELOPMENT AND EVALUATION OF HERBAL GEL OF *BALIOSPERMUM MONTANUM*

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ABSTRACT

The present study aimed to formulate, develop, and evaluate a herbal gel containing hydroalcoholic extract of Baliospermum montanum. The extract was prepared and showed a percentage yield of 12.5% (w/w). Phytochemical screening revealed the presence of important bioactive constituents such as alkaloids, glycosides, flavonoids, phenols, saponins, proteins, carbohydrates, and diterpenes. The total phenolic and flavonoid contents were found to be 0.96 mg/100 mg and 0.82 mg/100 mg, respectively. Six different gel formulations (HG1–HG6) were prepared using Carbopol 940 as a gelling agent. All formulations exhibited acceptable physical properties including good homogeneity, smooth texture, and absence of clogging. The pH of formulations was found to be within the suitable range for skin application. Among all formulations, HG5 showed optimum characteristics with appropriate viscosity, spreadability, and highest flavonoid content. The *in-vitro* drug release study of HG5 demonstrated a sustained release pattern with 98.6% drug release within 120 minutes. The antimicrobial activity of the optimized formulation showed significant inhibitory effects against *Streptococcus mutans* and *Candida albicans*, although slightly lower than standard drugs. The results suggest that the formulated herbal gel possesses good physicochemical properties and promising antimicrobial activity, indicating its potential as an effective topical therapeutic agent.

Keywords: *Baliospermum montanum*, herbal gel, Carbopol 940, phytochemical screening, flavonoids, phenolic content, *in-vitro* drug release, antimicrobial activity, topical formulation.

INTRODUCTION

Herbal drug delivery systems have gained significant attention in recent years due to their safety, efficacy, biocompatibility, and minimal side effects compared to synthetic formulations. Among various topical delivery systems, herbal gels are widely preferred because of their ease of application, better patient compliance, non-greasy nature, and ability to deliver active constituents directly to the site of action. They also provide controlled release of drug molecules and enhance therapeutic effectiveness (Saraf, 2010).

Baliospermum montanum (family: Euphorbiaceae), commonly known as Danti, is an important medicinal plant extensively used in traditional systems of medicine such as Ayurveda. It is known for its purgative, anti-inflammatory, antimicrobial, hepatoprotective, and wound healing properties (Rout *et al.*, 2017). The plant contains several bioactive phytoconstituents including diterpenoids, flavonoids, alkaloids,

and glycosides, which contribute to its diverse pharmacological activities.

Inflammatory skin conditions and microbial infections are common dermatological problems that require effective topical treatment. Herbal gels offer a promising approach for delivering plant-based actives in a stable and effective dosage form. In this context, the formulation of a gel containing *Baliospermum montanum* extract can enhance its topical application, improve skin absorption, and provide localized therapeutic action (Joe *et al.,* 2015).

The present study aims to formulate, develop, and evaluate an herbal gel of *Baliospermum montanum* extract. The objective is to assess its physicochemical properties, stability, and potential for topical therapeutic use, thereby providing a scientific basis for its traditional medicinal claims.

MATERIALS AND METHODS

Methods

Extraction by maceration process

50 gram roots of *Baliospermum montanum* shade dried plant material were coarsely powdered and subjected to extraction. Defatted roots of *Baliospermum montanum* were exhaustively extracted with hydroalcoholic solvent (Methanol: Aqueous; 60:40v/v) by maceration method. The extract was evaporated above their boiling points. Finally, the percentage yields were calculated of the dried extracts (Ansari, 2001; Mukherjee, 2007).

Determination of percentage yield

The percentage yield of each extract was calculated by using following formula:

$$\textbf{Percentage Yield} = \frac{Weight\ of\ Extract}{Weight\ of\ Powder\ drug\ taken} x\ 100$$

Phytochemical screening

Medicinal plants are resources of traditional medicines and many of the modern medicines are produced indirectly from plants. Phytochemical constituents are of two type primary bioactive constituents (chlorophyll, proteins, amino acids, sugar etc.) and secondary bioactive constituents include (alkaloids, terpenoids, phenols, flavonoids). Phytochemical examinations were carried out for all the extracts as per the standard methods (Khandelwal, 2005; Kokate, 1994).

Total phenolic content estimation

The total phenolic content of the extract was determined by the modified folin-ciocalteu method. 10 mg Gallic acid was dissolved in 10 ml methanol, various aliquots of 10-50µg/ml was prepared in methanol. 10 mg of dried extract was dissolved in 10 ml methanol and filter. Two ml (1mg/ml) of this extract was for the estimation of phenol. 2 ml of extract and each standard was mixed with 1 ml of folin-ciocalteu reagent (previously diluted with distilled water 1:10 v/v) and 1 ml (7.5g/l) of sodium carbonate. The mixture was vortexed for 15s and allowed to stand for 10min for colour development. The absorbance was measured at 765 nm using a spectrophotometer (Parkhe and Bharti, 2019).

Quantitative estimation of bioactive compounds

Total flavonoids content estimation

Determination of total flavonoids content was based on aluminium chloride method. 10 mg quercetin was dissolved in 10 ml methanol, and various aliquots of 5-25µg/ml were prepared in methanol. 10 mg of dried extract was dissolved in 10 ml methanol and filter. Three ml (1mg/ml) of this extract was for the

estimation of flavonoids. 1 ml of 2% $AlCl_3$ solution was added to 3 ml of extract or each standard and allowed to stand for 15min at room temperature; absorbance was measured at 420 nm (Parkhe and Bharti, 2019).

Formulation development of herbal gel

Measured quantity of methyl paraben, glycerin, polyethylene glycol and hydroalcoholic extract of *Baliospermum montanum* were dissolved in about 35 ml of water in beaker and were stirred at high speed using mechanical stirrer. Then Carbopol 940 was added slowly to the beaker containing above liquid while stirring. Neutralized the solution by slowly adding triethanolamine solution with constant stirring until the gel is formed (Nand *et al.*, 2012).

Evaluation of herbal gel

Appearance and consistency:

The physical appearance was visually checked for the texture of herbal gel formulations for color, odor and texture (Yamini and Onesimus, 2013).

Washability

Formulations were applied on the skin and then ease and extent of washing with water were checked manually and observed.

Extrudability determination of formulations

The herbal gel formulations were filled into collapsible metal tubes or aluminium collapsible tubes. The tubes were pressed to extrude the material and the extrudability of the formulation was checked (Bhaskar *et al.*, 2009).

Determination of Spreadability

Principle: An important criterion for gels is that it must possess good spreadability. Spreadability is a term expressed to denote the extent of area to which the gel readily spreads on application to skin. The therapeutic efficacy of a formulation also depends on its spreading value. A special apparatus has been designed to study the spreadability of the formulations. Spreadability is expressed in terms of time in seconds taken by two slides to slip off from formulation, placed between, under the application of a certain load. Lesser the time taken for the separation of two slides, better the spreadability.

Method:

Two glass slides of standard dimensions (6×2) were selected. The gel formulation whose spreadability had to be determined was placed over one of the slides. The second slide was placed over the slide in such a way that the formulation was sandwiched between them across a length of 6 cms along the slide. 100 grams of weight was placed up on the upper slide so that the gel formulation between the two slides was traced uniformly to form a thin layer. The weight was removed and the excess of the gel formulation adhering to the slides was scrapped off. The lower slide was fixed on the board of the apparatus and one end of the upper slide was tied to a string to which 20 gram load could be applied 50with the help of a simple pulley. The time taken for the upper slide to travel the distance of 6 cms and separate away from lower slide under the direction of the weight was noted. The experiment was repeated and the average of 6 such determinations was calculated for each gel formulation.

$$\text{Spreadability} = \frac{m.l}{t}$$

Where, S=Spreadability (gcm/sec)

m = weight tied to the upper slide (20 grams)

l= length of glass slide (6cms).

t = time taken is seconds.

Determination of pH

The pH of the gels was determined by digital pH meter. One gram of gel was dissolved in 25 ml of distilled water and the electrode was then dipped in to gel formulation until constant reading obtained. And constant reading was noted. The measurements of pH of each formulation were replicated two times (Bhalani and Shah, 2015).

Flavonoids content

The drug content was determined by taking 1gm of gel in 10 ml volumetric flask diluted with methanol. 3 ml of stock solution was mixed with 1 ml of 2% $AlCl_3$ solution. The mixture was vortexed for 15s and allowed to stand for 10min for colour development. The absorbance was measured at 420 nm using a spectrophotometer.

***In vitro* drug diffusion study**

The *in-vitro* diffusion study is carried by using franz diffusion cell. Egg membrane is taken as semi permeable membrane for diffusion. The Franz diffusion cell has receptor compartment with an effective volume approximately 60 mL and effective surface area of permeation 3.14sq.cms. The egg membrane is mounted between the donor and the receptor compartment.

A two cm^2 size patch taken and weighed then placed on one side of membrane facing donor compartment. The receptor medium is phosphate buffer pH 7.4. The receptor compartment is surrounded by water jacket so as to maintain the temperature at 32 ± 0.5°C. Heat is provided using a thermostatic hot plate with a magnetic stirrer. The receptor fluid is stirred by Teflon coated magnetic bead which is placed in the diffusion cell.

During each sampling interval, samples are withdrawn and replaced by equal volumes of fresh receptor fluid on each sampling. The samples withdrawn are analyzed spectrophotometrically at wavelength 282nm of drug.

***In vitro* antimicrobial activity of herbal gel**

Agar well-diffusion method was followed to determine the antimicrobial activity (Bauer *et al.,* 1966). Nutrient agar (NA) plates were swabbed (sterile cotton swabs) with fresh broth culture of bacteria. Wells (6mm diameter) were made in each of these plates using sterile cork borer. 100mg/ml, 50mg/ml and 25mg/ ml solution was prepared of extracts. About 100 µl of different concentrations of leaves, root and stem extract were added sterile micropipette into the wells and allowed to diffuse at room temperature for 2hrs. Control experiments comprising inoculums distilled water were set up. The plates were incubated at 37°C for 24 h for bacterial pathogens. The diameter of the inhibition zone (mm) was measured and the activity index was also calculated. Triplicates were maintained and the experiment was repeated thrice, for each replicates the readings were taken in three different fixed directions and the average values were recorded.

RESULTS AND DISCUSSION

The present study focused on the formulation, development, and evaluation of a herbal gel containing hydroalcoholic extract of *Baliospermum montanum*. The successful preparation of gel formulations (HG1–HG6) using Carbopol 940 as a gelling agent demonstrated the suitability of this polymer for topical drug delivery systems. The method adopted ensured uniform dispersion of

ingredients and formation of a stable gel upon neutralization with triethanolamine.

The percentage yield of the hydroalcoholic extract was found to be 12.5% (Table 2), indicating efficient extraction of phytoconstituents. Phytochemical screening (Table 3) revealed the presence of alkaloids, glycosides, flavonoids, phenols, saponins, proteins, carbohydrates, and diterpenes, while sterols and tannins were absent. These bioactive constituents are known to contribute to antimicrobial and anti-inflammatory activities, supporting the therapeutic potential of the formulation.

The total phenolic and flavonoid contents were found to be 0.96 mg/100 mg and 0.82 mg/100 mg respectively (Table 4), indicating a good presence of antioxidant compounds. These phytoconstituents may play a key role in enhancing wound healing and antimicrobial activity of the gel.

All formulations showed acceptable physical characteristics (Table 5), with light brown color, smooth texture, good homogeneity, and absence of clogging, indicating uniform distribution of the extract. The washability of all formulations was good, which is desirable for topical preparations, while extrudability was found to be good in HG4 and HG5, indicating ease of application from tubes (Table 6).

The evaluation of spreadability, pH, and viscosity (Table 7) showed that all formulations were within acceptable limits for topical application. The pH ranged from 5.3 to 7.2, which is compatible with skin pH, minimizing the risk of irritation. Viscosity increased with increasing concentration of Carbopol 940, which directly influenced the spreadability of the gel. Among all formulations, HG5 showed optimum viscosity (5541±09 cps) and acceptable spreadability, indicating better consistency and application properties. Additionally, HG5 exhibited the highest flavonoid content (88.6±0.2%), suggesting better incorporation and retention of active constituents.

The in-vitro drug release study of the optimized formulation HG5 (Table 8) showed a sustained and controlled release pattern, with 98.6% drug release at 120 minutes. This indicates effective diffusion of active constituents from the gel matrix, which is essential for prolonged therapeutic action.

The antimicrobial activity of the optimized formulation HG5 (Table 10) demonstrated significant inhibitory effects against *Streptococcus mutans* and *Candida albicans*. The zone of inhibition increased with concentration, with maximum activity observed at 100 mg/ml (15±0.5 mm and 14.3±0.74 mm, respectively). Although the activity was comparatively lower than standard drugs such as ciprofloxacin and fluconazole (Table 9), the herbal gel still exhibited appreciable antimicrobial potential, which can be attributed to the presence of flavonoids, phenols, and other phytoconstituents.

The formulation HG5 was found to be the optimized batch based on physicochemical parameters, drug release profile, and antimicrobial activity. The study confirms that *Baliospermum montanum* extract can be effectively incorporated into a gel formulation, providing a promising herbal alternative for topical antimicrobial therapy. Further studies on stability and in-vivo evaluation are recommended to establish its clinical efficacy.

Table 1: Formulation of herbal gel

Ingredients	HG1	HG 2	HG3	HG4	HG5	HG6
Baliospermum montanum extract	1gm	1gm	1gm	1gm	1gm	1gm
Carbopol 940	0.25mg	0.5mg	0.75mg	1.0 gm	1.25 gm	1.5 gm
Polyethylene glycol	0.2ml	0.2ml	0.2ml	0.2ml	0.2ml	0.2ml
Methyl paraben	0.08mg	0.08mg	0.08mg	0.08mg	0.08mg	0.08mg
Triethanolamine	1.0ml	1.0ml	1.0ml	1.0ml	1.0ml	1.0ml
Distilled Water (q.s)	100ml	100ml	100ml	100ml	100ml	100ml

*HG = Herbal gel

Table 2: Results of percentage yield of extract of *Baliospermum montanum*

Hydroalcoholic extract	Weight of extract	Percentage yield (w/w)
Baliospermum montanum	6.25	12.5%

Table 3: Result of phytochemical screening of extract of *Baliospermum montanum*

S. No.	Constituents	Hydroalcoholic extract
1.	Alkaloids A) Wagner's Test: B) Hager's Test:	 +Ve -Ve
2.	Glycosides A) Legal's Test:	 +Ve
3.	Flavonoids A) Lead acetate Test: B) Alkaline Reagent Test:	 +Ve +Ve
4.	Saponins A) Froth Test:	 +Ve
5.	Phenol A. Ferric Chloride Test: B. FC reagent test:	 +Ve +Ve
6.	Proteins A) Xanthoproteic Test:	 +Ve
7.	Carbohydrate A) Fehling's Test: B) Benedict test:	 +Ve -Ve
8.	Diterpenes A) Copper acetate Test:	 +Ve
9.	Sterols	-Ve
10.	Tannins	

	A) Gelatin test:	-Ve

Table 4: Estimation of total phenolic and flavonoids content of *Baliospermum montanum*

S. No.	Total phenol content (mg/100mg of dried extract)	Total flavonoids content (mg/ 100 mg of dried extract)
1.	0.96	0.82

Table 5: Results of physical appearance

Formulation	Colour	Clogging	Homogeneity	Texture
HG1	Light Brown	Absent	Good	Smooth
HG2	Light Brown	Absent	Good	Smooth
HG3	Light Brown	Absent	Good	Smooth
HG4	Light Brown	Absent	Good	Smooth
HG5	Light Brown	Absent	Good	Smooth
HG6	Light Brown	Absent	Good	Smooth

Table 6: Results of Washability and Extrudability

Formulation	Washability	Extrudability
HG1	Good	Average
HG2	Good	Average
HG3	Good	Average
HG4	Good	Good
HG5	Good	Good
HG6	Good	Average

Table 7: Results of spreadability, pH and Viscosity

Formulation	Spreadability (gcm/sec)	Determination of pH	Viscosity (cps)	Flavonoids content (%)
HG1	17.4±3	6.7±0.2	3541±15	70.4±0.1
HG2	21.9±1	7.1±0.3	4617±17	75.6±0.5
HG3	20.5±3	5.3±0.1	4365±23	81.5±0.3
HG4	19.7±1	7.0±0.4	3473±12	72.5±0.1
HG5	12.6±2	6.9±0.2	5541±09	88.6±0.2
HG6	23.1±1	7.2±0.1	5279±18	69.3±0.4

***Mean±S.D., Average of three determinations**

Table 8: Results of *In-vitro* drug release study of herbal gel formulation (HG5)

S. No.	Time (Min.)	Percentage drug release
1.	15	22.1±0.4
2.	30	54.6±0.9
3.	60	70.5±0.1
4.	90	87.2±0.3
5.	120	98.6±0.2

Table 9: Antimicrobial activity of Ciprofloxacin against selected microbes

S. No.	Name of drug	Name of microbes	Zone of Inhibition (mm)		
			10 µg/ml	20 µg/ml	30 µg/ml
1.	Ciprofloxacin	*Streptococcus mutans*	16±0.5	20±0.86	22±0.5
2.	Fluconazole	*Candida albicans*	14.6±0.94	18.3±0.5	20.6±0.47

***Average of three determination**

Table 10: Antimicrobial activity of optimized herbal gel (HG5) against selected microbes

S. No.	Name of microbes	Zone of inhibition (mm)		
		25mg/ml	50 mg/ml	100mg/ml
1.	*Streptococcus mutans*	10±0.47	13±0.94	15±0.5
2.	*Candida albicans*	11±0.86	12±0.57	14.3±0.74

***Average of three determination**

CONCLUSION

The herbal gel of *Baliospermum montanum* was successfully formulated using Carbopol 940 and showed satisfactory physicochemical properties such as good homogeneity, appropriate pH, viscosity, and spreadability. Phytochemical analysis confirmed the presence of bioactive compounds like flavonoids and phenols, contributing to its therapeutic potential. Among all formulations, HG5 was identified as the optimized batch based on its superior characteristics. The formulation exhibited controlled and sustained drug release profile. It also demonstrated appreciable antimicrobial activity against selected microorganisms.

DECLARATION OF INTEREST

The authors declare no conflicts of interests. The authors alone are responsible for the content and writing of this article.

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